

UNITED STATES DISTRICT COURT  
DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 25-1319
	)	
STERI-TECH, INC.,	)	
	)	
Defendant.	)	

**COMPLAINT**

The United States of America, by authority of the Attorney General of the United States and through the undersigned attorneys, acting at the request of the Administrator of the United States Environmental Protection Agency (EPA), files this complaint and alleges as follows:

**NATURE OF ACTION**

1. This is a civil action brought against Steri-Tech, Inc. (“Steri-Tech” or “Defendant”) pursuant to Clean Air Act (CAA) Section 113(b), as amended, 42 U.S.C. § 7413(b), to obtain injunctive relief and civil penalties for violations of CAA Section 112, 42 U.S.C. § 7412, and (a) the implementing CAA regulations at 40 C.F.R. Part 63, Subpart O (Ethylene Oxide Emission Standards for Sterilization Facilities) and (b) the provisions of the federally enforceable Puerto Rico State Implementation Plan that incorporate the Puerto Rico Regulations for the Control of Atmospheric Pollution (RCAP) operation permit requirements. The violations alleged in the complaint occurred, and certain violations continue to occur, at

Defendant's ethylene oxide (EtO) sterilization facility in Salinas, Puerto Rico ("Salinas Facility" or "Facility").

### **JURISDICTION AND VENUE**

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1355 and under CAA Section 113(b), 42 U.S.C. § 7413(b).

3. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1395 and under CAA Section 113(b), 42 U.S.C. § 7413(b), because Defendant resides within this District and because the violations that constitute the basis of this complaint occurred and are occurring at Defendant's facility located in the District.

### **NOTICE**

4. The United States provided notice of the commencement of this action to the Commonwealth of Puerto Rico as required by CAA Section 113(b), 42 U.S.C. § 7413(b).

### **AUTHORITY**

5. The United States has authority to bring this action on behalf of the Administrator of EPA under 28 U.S.C. §§ 516 and 519 and CAA Section 305, 42 U.S.C. § 7605.

### **DEFENDANT**

6. Steri-Tech is a corporation incorporated under the laws of Puerto Rico and headquartered in Salinas, Puerto Rico. Steri-Tech operates the Salinas Facility, an EtO sterilization facility located at State Road 701 Km 0.7, Salinas Industrial Park, Salinas, Puerto Rico.

7. Steri-Tech is a "person," as defined in CAA Section 302(e), 42 U.S.C. § 7602(e).

## **STATUTORY AND REGULATORY BACKGROUND**

8. The Clean Air Act establishes a regulatory scheme designed to protect and enhance the quality of the nation's air, so as to promote the public health and welfare and the productive capacity of its population. 42 U.S.C. § 7401(b)(1).

### **A. National Emission Standards for Hazardous Air Pollutants**

#### **1. General Provisions**

9. Under CAA Section 112(b), 42 U.S.C. § 7412(b), Congress established a list of hazardous air pollutants ("HAPs") believed to cause adverse health or environmental effects.

10. EtO is a listed HAP under CAA Section 112(b)(1), 42 U.S.C. § 7412(b)(1).

11. Under CAA Section 112(c), 42 U.S.C. § 7412(c), Congress directed EPA to publish a list of all categories and subcategories of, *inter alia*, area sources of HAPs.

12. "Area source" is defined as any stationary source of HAPs that is not a major source. 42 U.S.C. § 7412(a)(2).

13. "Major source" is defined as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any HAP or 25 tons per year or more of any combination of HAPs. 42 U.S.C. § 7412(a)(1).

14. "Stationary source" is defined as any building, structure, facility, or installation which emits or may emit any air pollutant. 42 U.S.C. § 7412(a)(3) (incorporating the definition of "stationary source" found at 42 U.S.C. § 7411(a)(3)).

15. Under CAA Section 112(d)(1), 42 U.S.C. § 7412(d)(1), Congress directed EPA to promulgate regulations establishing emission standards for each category or subcategory of, among other things, area sources of HAPs listed under Section 112(c). Such emission standards

require the maximum degree of reduction in emissions of hazardous air pollutants that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for the new or existing sources in the category or subcategory to which the emission standard applies. 42 U.S.C. § 7412(d)(2).

16. These emission standards are known as the National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Source Categories.

17. Under CAA Section 112(i)(3)(A), 42 U.S.C. § 7412(i)(3)(A), no person may operate a source in violation of any emissions standard, limitation, or regulation issued pursuant to CAA Section 112.

## **2. Subpart O - National Emission Standards for Ethylene Oxide Sterilization Facilities**

18. Pursuant to CAA Section 112(c), 42 U.S.C. § 7412(c), EPA identified ethylene oxide commercial sterilization and fumigation operations as a source category of HAPs. Pursuant to CAA Section 112(d), 42 U.S.C. § 7412(d), EPA promulgated NESHAP for various source categories. 40 C.F.R. Part 63.

19. NESHAP Subpart O identifies Ethylene Oxide Emissions Standards for Sterilization Facilities. 40 C.F.R. Part 63, Subpart O. NESHAP Subpart O was enacted on December 6, 1994 (“Subpart O (1994)”). 59 Fed. Reg. 62589 (Dec. 6, 1994).

20. NESHAP Subpart O was amended on November 2, 2001. 66 Fed. Reg. 55583 (Nov. 2, 2001). All citations to Subpart O in this Complaint are to the 2001 amended regulations unless otherwise noted.

21. NESHAP Subpart O was amended again on April 5, 2024 (“Subpart O (2024)”). 89 Fed. Reg. 55583 (April 5, 2024). Compliance by existing sterilization facilities with the

revised emissions reduction standards in Subpart O (2024) is not required until at least April 6, 2026. This Complaint does not assert violations of Subpart O (2024).

22. Pursuant to Subpart O, with certain exceptions not applicable here, all sterilization sources using one ton of EtO over a consecutive 12-month period in sterilization or fumigation operations are subject to the emission standards in 40 C.F.R. § 63.362. 40 C.F.R. § 63.360(a).

23. Owners and/or operators of sterilization sources that use one ton of EtO over a consecutive 12-month period must reduce EtO emissions to the atmosphere from each sterilization chamber vent by at least 99%. 40 C.F.R. § 63.362(c).

24. Owners and/or operators of sterilization sources that use 10 tons of EtO over a consecutive 12-month period must reduce EtO emissions to the atmosphere from each aeration room vent by at least 99% or to a maximum concentration of one part per million by volume (ppmv), whichever is less stringent. 40 C.F.R. § 63.362(d).

25. Owners and/or operators of sterilization sources subject to emissions standards in 40 C.F.R. § 63.362 must conduct an initial performance test using the procedures listed in 40 C.F.R. § 63.7 (according to the applicability in Table 1 of 40 C.F.R. § 63.360), the procedures listed in 40 C.F.R. § 63.363, and the test methods listed in 40 C.F.R. § 63.365. 40 C.F.R. § 63.363(a)(1). Owners and/or operators must use the procedures set forth in 40 C.F.R. § 63.363 to determine initial compliance with the emission limits under 40 C.F.R. §§ 63.362(c) and (d), the sterilization chamber vent standard and aeration room vent standard. 40 C.F.R. §§ 63.363(b) and (c).

26. Facilities with thermal oxidizers have an operating limit for that control device consisting of a “baseline temperature” initially established as the oxidation temperature at the

exhaust point from the thermal oxidation unit averaged over three test runs. Subpart O (1994), 40 C.F.R. §§ 63.363(b)-(c) and 63.363(f)(1)-(2).

27. A facility subject to emissions standards in 40 C.F.R. § 63.362 must demonstrate continuous compliance with each operating limit and work practice standard required under 40 C.F.R. § 63.363, according to the methods specified in 40 C.F.R. § 63.364, except during periods of startup, shutdown, and malfunction. 40 C.F.R. § 63.363(f).

28. An owner and/or operator of a source subject to the emissions standards in 40 C.F.R. § 63.362 must comply with the monitoring requirements in 40 C.F.R. §§ 63.364 and 63.8, according to the applicability in Table 1 of 40 C.F.R. § 63.360. 40 C.F.R. § 63.364(a)(1).

29. Sterilization facilities complying with 40 C.F.R. §§ 63.363(b) or (c) by using catalytic oxidation or thermal oxidation, must continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in 40 C.F.R. § 63.364(c)(4), or comply with 40 C.F.R. § 63.364(e) (direct measurement of EtO). 40 C.F.R. § 63.364(c).

30. Such facilities must use a data acquisition system for the temperature monitor to compute and record a daily average oxidation temperature from 15 minute or shorter period temperature values. Strip chart data must be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature. 40 C.F.R. § 63.364(c).

31. Owners and/or operators of a source subject to the emissions standards in 40 C.F.R. § 63.362 must comply with the performance testing requirements in 40 C.F.R. § 63.365 and Subpart A, 40 C.F.R. § 63.7, according to the applicability in Table 1 of 40 C.F.R. § 63.360. 40 C.F.R. § 63.365(a).

### **3. Subpart A – Performance Testing Requirements**

32. Performance tests must, among other things, be conducted under such conditions as the EPA Administrator specifies to the owner or operator based on representative performance (*i.e.*, performance based on normal operating conditions) of the affected source. 40 C.F.R. § 63.7(e)(1).

33. Unless otherwise specified in a relevant standard or test method, each performance test must consist of three separate runs using the applicable test method. Each run must be conducted for the time and under the conditions specified in the relevant standard. For the purpose of determining compliance with a relevant standard, the arithmetic mean of the results of the three runs will apply. 40 C.F.R. § 63.7(e)(3).

### **4. Violations of the NESHAPs**

34. After the effective date of any emission standard, limitation, or regulation promulgated pursuant to CAA Section 112, no person may operate such source in violation of such standard, limitation, or regulation. 42 U.S.C. § 7412(i)(3).

### **B. Puerto Rico State Implementation Plan and Regulations for the Control of Atmospheric Pollution**

35. CAA Section 110, 42 U.S.C. § 7410, requires each state to adopt and submit to EPA for approval a plan that provides for the implementation, maintenance, and enforcement of each of the national ambient air quality standards promulgated pursuant to CAA Section 109, 42 U.S.C. § 7409. CAA Section 110(a), 42 U.S.C. § 7410(a), further provides that each such plan must, among other things, include enforceable emission limitations and other control measures, means, or techniques, as may be necessary or appropriate to meet the applicable CAA requirements. Such plans, once approved by EPA, are known as State Implementation Plans

(SIPs) and they are federally enforceable by EPA pursuant to CAA Section 113(a)(1) and (b), 42 U.S.C. § 7413(a)(1) and (b).

36. Pursuant to Puerto Rico Environmental Public Policy Act (Law No. 9, June 18, 1970, as amended), the Puerto Rico Environmental Quality Board (EQB) developed the Puerto Rico Regulations for the Control of Atmospheric Pollution (RCAP). In 2017, EQB's functions and powers were transferred to the Puerto Rico Department of Natural and Environmental Resources (DNER).

37. On January 22, 1997, EPA approved the RCAP, as submitted to EPA on September 29, 1995, as part of the federally approved SIP for the Commonwealth of Puerto Rico. 62 Fed. Reg. 3211. At all times relevant to this Complaint, the federally approved SIP for the Commonwealth of Puerto Rico has included the applicable RCAP provisions cited herein.

38. RCAP Rule 102 defines "Air Pollutant" as, among other things, fumes, mist, vapors, gases, physical or chemical substances, or any combination thereof, but not including uncombined water vapor.

39. RCAP Rule 102 defines "Air Pollution Control Equipment" as any process equipment, device, and all appurtenances thereto, used for eliminating, reducing, or controlling the emission of any air pollutant.

40. RCAP Rule 102 defines "Applicable Rules and Regulations" as all rules and regulations promulgated under the Environmental Public Policy Act and the Clean Air Act for the control of atmospheric pollution, including, among other things, all requirements established by the RCAP or any other applicable laws or regulations of the Commonwealth of Puerto Rico.

41. RCAP Rule 102 defines "Owner or Operator" as any person who owns, leases, operates, controls or supervises a source or facility.



42. RCAP Rule 102 defines “Person” as any person, natural or juridical, or group of persons, private or public, including agencies, government bodies, municipalities and public or quasi-public corporations.

43. RCAP Rule 102 defines “Source” as any structure, building, facility or installation (or combination thereof), which is located on one or more contiguous or adjacent properties under common ownership or operation, which emits or may emit any air pollutants.

44. Pursuant to RCAP Rule 203(A) (Permit to construct a source or modification), no person may construct or modify a source without a permit from DNER.

45. Pursuant to RCAP Rule 203(B) (Standards for granting a permit to construct), a permit to construct or modify a source may be granted only if the applicant demonstrates, among other things, that the source will be able to comply with all applicable rules and regulations and that air pollutant emissions from the source will be limited in accordance with applicable rules and regulations.

46. Pursuant to RCAP Rule 203(C) (Application for a permit to construct), each application for a permit to construct or modify a source must include, among other things, detailed plans and specifications of the emissions and of any air pollution control equipment or measures proposed to be installed and constructed to achieve compliance with applicable rules and regulations.

47. Pursuant to RCAP Rule 204(A)(1) (Permit to operate a source; permit required), no person may operate or cause the operation of a source or air pollution control equipment without a permit to operate or a temporary permit to operate from DNER.

48. Pursuant to RCAP Rule 401(B), no person may cause or permit the emission of any air pollutant in violation of “applicable rules and regulations.”

### **C. Enforcement of the CAA**

49. CAA Section 113(b), 42 U.S.C. § 7413(b), authorizes EPA to commence a civil action for injunctive relief and/or civil penalties against any person who has violated any requirement or prohibition of the CAA or regulations promulgated thereunder, or who has violated any applicable implementation plan or permit.

50. CAA Section 113(b), 42 U.S.C. § 7413(b), further authorizes civil penalties of up to \$25,000 per day for each violation of the CAA. The Debt Collection Improvement Act, 31 U.S.C. § 3701 *et seq.*, requires EPA to periodically adjust its civil penalties for inflation. EPA adopted and revised regulations entitled *Adjustment of Civil Monetary Penalties for Inflation*, 40 C.F.R. Part 19, to upwardly adjust the maximum civil penalty under the CAA. For each violation that occurs after November 2, 2015, penalties of up to \$124,426 per day may be assessed where penalties are assessed after January 8, 2025. 90 Fed. Reg. 1375 (Jan. 8, 2025).

### **GENERAL ALLEGATIONS**

#### **The Salinas Facility**

51. Steri-Tech, Inc. is the “owner” and “operator,” as defined in CAA Section 112(a)(9), 42 U.S.C. § 7412(a)(9), and RCAP Rule 102, of the Salinas Facility located in Salinas, Puerto Rico.

52. The Salinas Facility has been in operation since 1986.

53. The Salinas Facility constitutes a “stationary source” within the meaning of CAA Section 112(a)(3), 42 U.S.C. § 7412(a)(3), an “area source” of HAPs within the meaning of CAA Section 112(a)(2), 42 U.S.C. § 7412(a)(2), and a “source” within the meaning of RCAP Rule 102.

54. The Salinas Facility's sources of EtO air emissions include four sterilization chambers, including associated sterilization chamber vents, and four post-sterilization aeration rooms, including associated aeration room vents.

55. Steri-Tech operates or has operated within the time period relevant to this complaint air pollution control equipment, including a thermal oxidizer and a catalytic recuperative oxidizer, for eliminating, reducing, and controlling EtO emissions from the Facility.

56. The Facility uses more than 10 tons per year of EtO. According to Steri-Tech's annual EtO consumption logs, Steri-Tech used 69,713 pounds (34.85 tons) of EtO in 2023, 74,540 pounds (37.27 tons) of EtO in 2022, and 79,108 pounds (39.55 tons) of EtO in 2021.

#### **Regulatory Compliance and Permit History**

57. On November 29 through December 2, 1999, Steri-Tech conducted an initial performance test of its thermal oxidizer's control efficiency for EtO at the Facility's sterilization chambers and aeration rooms ("1999 Performance Test"). The results of the 1999 Performance Test were documented in a report dated January 2000 ("January 2000 Performance Test Report").

58. The January 2000 Performance Test Report stated that the thermal oxidizer, a Facility emission control device for EtO, is 100% efficient with respect to removing EtO when achieving a baseline operating temperature of 1,521°F.

59. Steri-Tech initially operated under a minor source operating permit, PFE-RG-63-0308-0006-I-II-O ("2009 Operation Permit"), with an effective date of December 10, 2009, and an expiration date of December 10, 2014. Following expiration of the 2009 Operation Permit, Steri-Tech sought renewal of the permit by DNER and responded to various information requests from DNER.

60. On April 28, 2021, DNER issued Steri-Tech a renewal minor source operating permit, PFE-RG-63-0715-0810-I-II-III-O (“April 2021 Operation Permit”), under RCAP Rule 204.

61. On November 8, 2021, DNER issued Steri-Tech a modification to the April 2021 Operation Permit, PFE-RG-63-0715-0810-I-II-III-O (“November 2021 Operation Permit”). This modification removed two boilers as alternative control devices for the Facility’s aeration rooms, leaving the thermal oxidizer as the only authorized air pollution control equipment for controlling EtO emissions from the Facility’s sterilization chambers and aeration rooms.

62. In response to an August 2022 request from Steri-Tech, on October 6, 2022, DNER issued another modified operation permit, PFE-RG-63-0715-0810-I-II-III-O (“2022 Operation Permit”), which authorizes Steri-Tech to operate a catalytic recuperative oxidizer as the sole emission control device for the Facility. The 2022 Operation Permit supersedes all previous versions of the operation permit, and it expires on April 28, 2026.

63. On March 28, 2025, DNER issued another modified operation permit, PFE-RG-63-0715-0810-I-II-III-O (“2025 Operation Permit”), which authorizes Steri-Tech to operate a thermal oxidizer as an alternate emission control device for the Facility, while retaining the catalytic recuperative oxidizer as the primary control device. The 2025 Operation Permit supersedes all previous versions of the operation permit, and it expires on April 28, 2026.

64. The 2009 Operation Permit, April 2021 Operation Permit, November 2021 Operation Permit, 2022 Operation Permit, and 2025 Operation Permit (collectively, the “Operation Permits”) each incorporate the “Ethylene Oxide Emissions Standards for Sterilization Facilities” (40 C.F.R. Part 63, Subpart O) as applicable requirements for the Facility, in addition to specifying removal efficiencies for pollution control equipment.

### **EPA Inspections and Enforcement**

65. EPA Region 2 has been investigating the Salinas Facility pursuant to its authority under CAA Section 114, 42 U.S.C. § 7414. EPA's investigation has included numerous site visits and inspections of the Facility from 2018 through the present; written and verbal information requests made to Steri-Tech regarding the Facility and its operations; and a review of Steri-Tech's records, data, and other information as provided to EPA in response to such information requests.

66. On December 12, 2018, EPA Region 2 conducted an on-site inspection of the Facility ("2018 Inspection").

67. On August 22, 2019, EPA issued an Information Request Letter to Steri-Tech, pursuant to CAA Section 114(a), 42 U.S.C. § 7414(a). Among other things, the Information Request Letter directed Steri-Tech to conduct a performance test of its thermal oxidizer.

68. On December 4, 2019, EPA Region 2, accompanied by inspectors from the EPA National Enforcement Investigation Center (NEIC), conducted an on-site inspection of the Facility ("2019 Inspection").

69. During the 2019 Inspection, EPA and NEIC inspectors conducted a walkthrough of the Facility, reviewed and requested information to evaluate Steri-Tech's compliance with Subpart O and the 2009 Operation Permit, and discussed with Steri-Tech's representatives alleged non-compliance found as a result of the 2018 Inspection.

70. On June 29, 2021, EPA issued a Notice of Violation (NOV) to Steri-Tech, Docket No. CAA-02-2021-1303 ("2021 NOV"), citing violations of the CAA and applicable requirements in NESHAP Subpart O and the RCAP. Steri-Tech and EPA held a conference to discuss the violations alleged in the 2021 NOV in July 2021.

71. On October 23, 2023, EPA issued an Administrative Compliance Order (“Order”), pursuant to CAA Section 113(a), 42 U.S.C. § 7413(a), to Steri-Tech for alleged violations of the CAA. Among other things, the Order directed Steri-Tech to conduct a performance test of its catalytic recuperative oxidizer and to disconnect the thermal oxidizer from its fuel source line and from the sterilization chambers and aeration rooms.

### **FIRST CLAIM FOR RELIEF**

#### **Failure to Reduce EtO Emissions by 99% at Each Sterilization Chamber Vent and Each Aeration Room Vent and Failure to Comply with the Daily Average Minimum Temperature Operating Limit for the Thermal Oxidizer Subpart O: 40 C.F.R. §§ 63.362(c) and (d), and 63.363(b)(3) and (f)**

72. Plaintiff realleges and incorporates by reference Paragraphs 1 through 71, as if fully set forth herein.

73. Pursuant to 40 C.F.R. §§ 63.362(c) and (d), an owner or operator of a sterilization source using 10 tons or more EtO within a consecutive 12-month period must reduce EtO emissions to the atmosphere by at least 99% from each sterilization chamber vent and by the less stringent of at least 99% reduction or to a maximum concentration of one ppmv from each aeration room vent.

74. Pursuant to Subpart O (1994), 40 C.F.R. §§ 63.363(b)(1)(ii), 63.363(c)(2), and 63.365(f), where an owner or operator seeks to comply with the EtO reduction requirements of 40 C.F.R. § 63.362(c) or (d) through use of a thermal oxidizer as an emission control device, the initial operating limit for such thermal oxidizer is established as the oxidation temperature at the exhaust point from the thermal oxidation unit averaged over three test runs.

75. Steri-Tech’s January 2000 Performance Test Report stated that its emission control system consisted of a thermal oxidizer fabricated by NAO, Inc. and the operating limit

was established from the average of three test runs as 1,521.2°F for the sterilization chamber and 1,500.9°F for the aeration rooms.

76. During the December 2018 Inspection, December 2019 Inspection, and related evaluations of Facility documents, EPA observed that Steri-Tech failed to continuously operate the thermal oxidizer at a temperature greater than or equal to 1500°F.

77. Steri-Tech continuously recorded thermal oxidizer temperatures on strip charts. Strip charts provided by Steri-Tech to EPA for the period September through November 2018, and September through November 2019, show that Steri-Tech failed to continuously operate the thermal oxidizer at a daily average temperature greater than or equal to 1500°F.

78. From at least June 15, 2019, through September 3, 2023, Steri-Tech failed to continuously comply with the daily average minimum temperature operating limit for its thermal oxidizer in violation of 40 C.F.R. § 63.363(b)(3) and (f).

79. On September 4, 2023, Steri-Tech ceased its use of the thermal oxidizer as an EtO emissions control device and commenced continuous operation of its catalytic recuperative oxidizer as its EtO emissions control device in its place.

80. Each day that Steri-Tech failed to comply with the daily average minimum temperature operating limit for its thermal oxidizer, it likewise failed to comply with the requirement to reduce emissions of EtO from each sterilization chamber vent and aeration room vent by at least 99%. 40 C.F.R. §§ 63.362(c) and (d), and 63.363(b)(3) and (f).

81. Operation of a source in violation of a standard, limitation, or regulation provided by NESHAP Subpart O constitutes a violation of CAA Section 112. 42 U.S.C. § 7412(i)(3).

82. The Operation Permits each identify the “Ethylene Oxide Emissions Standards for Sterilization Facilities” (40 C.F.R. Part 63, Subpart O) as applicable requirements for the

Facility, and the requirements of Subpart O are incorporated into the Operation Permits as if fully written therein. The violations of NESHAP Subpart O identified in Paragraphs 78 and 80, therefore, also constitute violations of the Facility's DNER Operation Permit in effect at the time of the violation.

83. Violation of the Operation Permit constitutes a violation of RCAP Rule 401(B), part of the EPA-approved Puerto Rico SIP.

84. Unless restrained by an order of this Court, the violation of the CAA alleged in this First Claim for Relief may recommence.

85. As provided in CAA Section 113(b), 42 U.S.C. § 7413(b), and pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 3701, and 40 C.F.R. § 19.4, the violations set forth above subject Steri-Tech to injunctive relief and civil penalties of up to \$124,426 per day for each violation.

## **SECOND CLAIM FOR RELIEF**

### **Failure to Calculate Daily Average Oxidation Temperatures Subpart O: 40 C.F.R. §§ 63.363(f) and 63.364(c)**

86. Plaintiff realleges and incorporates by reference Paragraphs 1 through 71, as if fully set forth herein.

87. Pursuant to 40 C.F.R. § 63.363(f), a facility must demonstrate continuous compliance with each operating limit and work practice standard required under 40 C.F.R. § 63.363, except during periods of startup, shutdown, and malfunction, according to the methods specified in 40 C.F.R. § 63.364.

88. 40 C.F.R. § 63.364(c) requires an owner or operator of a sterilization facility complying with 40 C.F.R. §§ 63.363(b) or (c) through the use of thermal oxidation to utilize a data acquisition system for the temperature monitor to compute and record a daily average



oxidation temperature from 15-minute or shorter period temperature values. Strip chart data must be converted to record a daily average oxidation temperature each day that any instantaneous temperature recording falls below the minimum temperature. *Id.*

89. During the December 2018 Inspection, December 2019 Inspection, and related evaluations of Facility documents, EPA observed that Steri-Tech failed to operate the thermal oxidizer at a temperature greater than or equal to 1500°F continuously, with instantaneous temperature recordings repeatedly falling below the minimum temperature.

90. On none of the occasions when instantaneous temperature recordings fell below the minimum temperature did Steri-Tech convert strip chart data to identify the daily average oxidation temperature. Steri-Tech lacked equipment at the Facility capable of converting the strip chart data to the daily average oxidation temperatures.

91. From at least June 15, 2019, through September 3, 2023, Steri-Tech failed to convert strip chart data to the daily average oxidation temperature each day that any instantaneous temperature recording at the thermal oxidizer fell below the minimum operating temperature, in violation of 40 C.F.R. §§ 63.363(f) and 63.364(c).

92. On September 4, 2023, Steri-Tech ceased its use of the thermal oxidizer as an EtO emissions control device and commenced continuous operation of its catalytic recuperative oxidizer as its EtO emissions control device in its place.

93. Operation of a source in violation of a standard, limitation, or regulation provided by NESHAP Subpart O constitutes a violation of CAA Section 112. 42 U.S.C. § 7412(i)(3).

94. The Operation Permits each identify the “Ethylene Oxide Emissions Standards for Sterilization Facilities” (40 C.F.R. Part 63, Subpart O) as applicable requirements for the Facility, and the requirements of Subpart O are incorporated into the Operation Permits as if

fully written therein. The violations of NESHAP Subpart O identified in Paragraph 91, therefore, also constitute violations of the Facility's DNER Operation Permit in effect at the time of the violation.

95. Violation of the Operation Permit constitutes a violation of RCAP Rule 401(B), part of the EPA-approved Puerto Rico SIP.

96. Unless restrained by an order of this Court, the violation of the CAA alleged in this Second Claim for Relief may recommence.

97. As provided in CAA Section 113(b), 42 U.S.C. § 7413(b), and pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 3701, and 40 C.F.R. § 19.4, the violations set forth above subject Steri-Tech to injunctive relief and civil penalties of up to \$124,426 per day for each violation.

### **THIRD CLAIM FOR RELIEF**

#### **Failure to Continuously Reduce EtO Emissions by Required 99.9% at Each Sterilization Chamber Vent and Each Aeration Room Vent RCAP Rule 401(B)**

98. Plaintiff realleges and incorporates by reference Paragraphs 1 through 71 as if fully set forth herein.

99. In response to an August 2022 request from Steri-Tech, on October 6, 2022, DNER issued the 2022 Operation Permit, permit number PFE-RG-63-0715-0810-I-II-III-O, which modified the prior permit and authorized Steri-Tech to operate a catalytic recuperative oxidizer as the sole emission control device for the Facility.

100. Section II of the 2022 Operation Permit requires Steri-Tech to operate the catalytic recuperative oxidizer with a minimum efficiency of 99.9% for removal of EtO.

101. Following various mechanical and operational difficulties, Steri-Tech commenced continuous operation of the catalytic recuperative oxidizer as its EtO emissions control device on September 4, 2023. Steri-Tech had submitted a performance test protocol for EPA review on August 22, 2023, and EPA approved the test protocol on September 29, 2023.

102. Steri-Tech conducted a performance test of its catalytic recuperative oxidizer on January 8, 2024. On April 5, 2024, Steri-Tech submitted a revised performance test report stating that the January 2024 performance test showed that the catalytic recuperative oxidizer only reduced EtO emissions to the atmosphere by approximately 93.5%.

103. Steri-Tech submitted a new performance test protocol in August 2024. Following revisions, EPA approved the new performance test protocol. Steri-Tech conducted a second performance test of the catalytic recuperative oxidizer from September 24 through 26, 2024. On November 8, 2024, Steri-Tech submitted a performance test report showing that the catalytic recuperative oxidizer was now reducing EtO emissions to the atmosphere from each sterilization chamber vent and aeration chamber vent by approximately 99.1%.

104. Neither the January 2024 performance test nor the September 2024 performance test performed by Steri-Tech showed its catalytic recuperative oxidizer achieving a minimum efficiency of 99.9% for removal of EtO.

105. The 2025 Operation Permit retained the requirement that Steri-Tech operate the catalytic recuperative oxidizer with a minimum efficiency of 99.9% for removal of EtO.

106. From September 4, 2023, through the present, Steri-Tech violated its 2022 Operation Permit and 2025 Operation Permit by failing to reduce EtO emissions to the atmosphere from each sterilization chamber vent and each aeration chamber vent by at least 99.9%.

107. CAA Section 113(b), 42 U.S.C. § 7413(b), provides that EPA may bring an action for injunctive relief and civil penalties when a person has violated any requirement or prohibition of an applicable SIP or permit.

108. Unless restrained by an order of this Court, the violation of the CAA alleged in this Third Claim for Relief will continue.

109. As provided in CAA Section 113(b), 42 U.S.C. § 7413(b), and pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 3701, and 40 C.F.R. § 19.4, the violations set forth above subject Steri-Tech to injunctive relief and civil penalties of up to \$124,426 per day for each violation.

#### **PRAYER FOR RELIEF**

WHEREFORE, based upon all the allegations contained in Paragraphs 1 through 109 above, the United States of America requests that this Court:

1. Permanently enjoin Steri-Tech from operating its EtO sterilization operations at the Salinas Facility inconsistently with the CAA, any applicable regulatory requirements, the Puerto Rico SIP, and the DNER operation permit;
2. Order Steri-Tech to remedy the past violations at the Salinas Facility by, among other things, complying with Subpart O of Part 63 of Title 40 of the Code of Federal Regulations;
3. Assess a civil penalty against Steri-Tech of up to \$124,426 per day for each violation occurring on or after November 3, 2015, and assessed on or after January 8, 2025;
4. Award Plaintiff its costs of this action; and

5. Grant such other relief as the Court deems just and proper.

Respectfully submitted,

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